UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,432	10/27/2003	Kathleen C.M. Campbell	SIU 7399	8934

321 7590 09/22/2006

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,432	CAMPBELL, KATHLEEN C.M.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *17 May 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 and 11-29 are presented for examination.

Applicant's Amendment filed July 10, 2006 has been received and entered into the present application. Applicant's Information Disclosure Statement (IDS) filed May 17, 2006 has also been received and entered into the application. As reflected by the attached, completed copy of form PTO/SB/08A (one page total), the Examiner has considered the cited reference.

Claims 1-9 and 11-29 remain pending and are under examination. Claims 1, 5-9, 11, 15-17, 20-22 and 29 are amended.

Applicant's arguments, filed July 10, 2006, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11 and 14-21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of methionine (D-, L- or DL-) for the treatment of alopecia, does not reasonably provide enablement for the use of any one or more of the "methionine-like" compounds encompassed by the formula of present claim 1, for the reasons already of record set forth at pages 4-14 of the previous Office Action dated March 8, 2006, of which said reasons are herein incorporated by reference.

Applicant has amended the claims to remove the limitation directed to the "prevention" of alopecia. In light of the fact that claims 12-13 and 22-29 are directed to the "treatment" of alopecia using methionine *per se* (i.e., D-, L- or DL-), which is enabled by the disclosure, the present rejection has been **withdrawn** as it was applied to claims 12-13 and 22-29.

Applicant states in response to the present rejection, "Beyond the common thioether group, the generically defined compound shares the basic molecular structure of methionine, and indeed is further characterized in the claim itself as 'containing a methionine or methionine-like moiety'. Thus, the specification and claims define a relatively narrow class of compounds having a structure that one skilled in the art would reasonably expect to be effective in the same manner as D-methionine. In view of the teaching provided by Applicant's disclosure, confirmation of enablement as to any particular species within this genus would require no more than routine experimentation...It is Applicant's understanding that the Examiner is citing the breadth of the claim alone as meeting the burden imposed by *Marzocchi*." (see Applicant's remarks at page 8)

Applicant's remarks have been fully considered, but are not persuasive.

As previously set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to

make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

Applicant is also reminded of MPEP §2164.08, which directs that all questions of enablement must be evaluated against the claimed subject matter. Concerning the breadth of a claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of enablement involves the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to use the *entire scope* of the claimed invention without undue experimentation.

The present rejection is not based exclusively on the breadth of the claims. Rather, the rejection is based upon the fact that Applicant has not provided adequate enabling direction as to how to use the entire scope of the "methionine-like" compounds presently claimed (please reference claim 1), since the specification is directed to the use of D-methionine and provides no evidentiary basis for extrapolating the results seen with D-methionine to the much larger and highly varied genus of "methionine-like" compounds presently claimed. Claim breadth alone is not a sufficient basis for concluding a lack of enabling direction; however, where the claims encompass such a large and variable genus of compounds, where only one has been exemplified, and the state of the art is sufficiently unpredictable such that one of ordinary skill in the art would have been skeptical to extrapolate the efficacy seen with a single species to this larger and more highly varied genus of compounds, a conclusion of a lack of enabling direction is appropriate.

Applicant's claims encompass compounds with a basic thioether core structure, but allow for hundreds, if not thousands, of permutations of this physical structure due to the numerous positions of substitution in the recited moieties (see present claim 1). Such substitutions give rise to an enormous number of compounds that are substantially different in physical and chemical structure such that the efficacy demonstrated with a single species, i.e., D-methionine, would not necessary be representative of such a vast and variable genus of compounds, depending on the substitutions present in the molecule. For example, heteroaromatic rings are known to have distinct chemical, structural and functional properties from, say, an unsubstituted lower alkyl moiety such that the skilled artisan would not have expected the same level of activity with a substituted heteroaromatic compound as he would from an unsubstituted lower alkyl compound. However, Applicant continues to assert that the present disclosure provides adequate enablement of the claimed subject matter and relies upon the exemplification of D-methionine in the present specification as a compound representative of the claimed genus.

It was known in the art at the time of the present invention that even compounds that share similar structural properties cannot be guaranteed to have the same level of activity. Such is the unpredictable nature of the pharmaceutical arts, as acknowledged by Remington's Pharmaceutical Sciences, which states, "Two-dimensional structural organic formulas are very poor means of representing the physical, chemical, or biologic properties of a molecule. Structural formulas merely depict the way the various atoms are strung together to from what is known as a *molecule*. Drugs that are strikingly similar in structure may demonstrate widely differing pharmacologic properties, while two drugs of apparently different structure can exhibit almost identical activity. Reference to Table I [see pages 421-424] easily confirms these facts.

There are many factors other than simple structural variation that have an effect on the activity of a drug." (see first paragraph, column 1, page 425) Such factors include, but are not limited to, molecular size, shape, ionization, charge distribution, solubility, interatomic distance, geometric and stereochemical configurations, and the rigidity or flexibility of the molecule (see pages 425-426)

This well-recognized unpredictability in the art must be taken into consideration when determining whether a disclosure fails to provide sufficient enabling direction for the claimed subject matter. As directed by the MPEP, the amount of guidance required to be present in the specification as originally filed is directly proportional to the amount of knowledge in the art as well as the unpredictability in the art. In other words, if little or nothing is known in the prior art about an aspect of the claimed invention and the art is unpredictable, the specification needs more detail and guidance as to how to use the invention in order to be enabling. Please reference *In re Fisher*, 417 F.2d 833, 839, 166 USPQ 18, 23 (CCPA 1970) and *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004).

Applicant's exemplification of the single species of D-methionine does not address the variability in physical and chemical structure of the claimed genus of compounds such that one of ordinary skill in the art would have been imbued with the reasonable expectation of success in treating alopecia with any one or more of the claimed "methionine-like" compounds of present claim 1. In fact, the variability in physical and chemical structure of the compounds encompassed by Applicant's claimed genus precludes the extrapolation of the exemplified results of D-methionine to this larger and much more highly varied genus of "methionine-like" compounds as a whole, absent any criteria or scientific or evidentiary basis upon which to rely.

As a result, the skilled artisan would not be able to readily determine what other compounds within the scope of those intended by Applicant would reasonably have possessed a therapeutic effect on alopecia in the absence of such evidence or guidance by the specification. In other words, the skilled artisan would have no alternative recourse but the undue burden of experimentation in order to determine those other "methionine-like" compounds that could be used in the presently claimed method.

It is well settled in patent law that in cases involving chemicals and chemical compounds, which differ radically in their properties, it must appear in an Applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result. Please reference *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940). Though Applicant's exemplification of D-methionine has been noted, this single working example is not sufficiently representative of the hundreds, if not thousands, of "methionine-like" compounds presently claimed. The exemplification of this single compound fails to provide basis for enabling the entire vast scope of compounds presently claimed without any evidence or reasoning by Applicant addressing the unpredictability in the pharmaceutical arts and how this single example is representative of the claimed genus as a whole. While the lack of multiple working embodiments cannot be the sole factor in determining enablement, the absence of substantial evidence commensurate in scope with the breadth of the presently claimed subject matter, in light of the unpredictable nature of the art and the limited direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole.

It is noted that Applicant is not required to enable each and every single embodiment encompassed by the claims. While the scope of the required enablement varies inversely with the degree of predictability involved, even in the unpredictable arts, such as pharmaceuticals and pharmacology, a disclosure of every operable species is not required. However, while a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, [please see *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971)], in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. Please see MPEP §2164.03. In the absence of additional disclosure, the skilled artisan would be required to perform an undue level of experimentation in order to determine these other species that would be capable of performing the claimed method.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re*

Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*." (emphasis added)

For these reasons, and those previously made of record, rejection of claims 1-9, 11 and 14-21 remains proper and is **maintained**.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that present claim 24 recites, "wherein said effective amount of said protective agent is administered simultaneously with said noise exposure", and present claim 25 recites, "wherein said effective amount of said protective agent is administered subsequently to said noise exposure", but does not clearly set forth how exposure to noise is related to the claim from which it depends, which is directed to the treatment of alopecia. In other words, Applicant has failed to clearly, precisely and deliberately set forth how the claim limitation to "noise exposure" further limits the claim from which it depends because any reference to noise is not found in independent claim 22.

For this reason, present claims 24-25 fail to reasonably apprise the skilled artisan of the metes and bounds of the subject matter for which Applicant is seeking protection. Accordingly,

the claims are properly rejected under 35 U.S.C. 112, second paragraph, for failing to meet the tenor and express requirements of this statute.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 11-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur et al. (EP 0008171; 1979) in view of Stedman's Medical Dictionary (Twenty-Second Edition; 1972).

Mathur et al. teaches a hair treatment composition comprising a monobasic acid, such as methionine (interpreted to be inclusive of D-, L- or DL- forms) or salts or esters thereof, together with an imidazole, a histidine or histidine derivative compound and a pharmaceutically acceptable carrier for topical administration (page 4, lines 13-16 and 21-28), for use in stimulating hair growth, restoring hair growth and/or reducing hair loss in humans (page 2, lines 1-4), wherein the alopecia may result from a variety of conditions, including X-ray treatment (page 3, lines 7-16).

Stedman's Medical Dictionary teaches that X-ray treatment is a type of radiation therapy (see page 1058).

The differences between the Mathur et al. reference and the presently claimed subject matter lie in that the reference fails to teach the presently claimed schedule of administration

(i.e., prior to, simultaneously with or subsequently to radiation exposure, see present claims 2-4, 23; or 36, 25, 6, 1, or 0.5 hours before to 0.5, 1, 6, 25 or 36 after radiation exposure, see present claims 5-9); the presently claimed dosage amounts (see present claims 15-17, 20-22 and 28-29); or the administration of a supplemental amount after the administration of the effective amount (see present claims 18 and 27).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

The determination of the optimum dosage regimen and schedule of administration to treat alopecia with the presently claimed active agent would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen and schedule of administration that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts and schedule of administration are not seen to be inconsistent with that which would have been determined by, and well within the routine skill of, the skilled artisan.

Regarding the optimization of the dosage regimen to maximize the efficacy of the active agent in treating alopecia, Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are directed to mg/kg body weight amounts and not percentages *per se*, such a motivation is nonetheless relevant.

Additionally, it is noted that the supplemental administration of the active composition following the administration of an effective amount of the composition (see present claims 18 and 27) would have been *prima facie* obvious to one of ordinary skill in the art motivated by the desire to prolong the therapeutic benefit of the composition to the patient receiving the composition and to also maximize the efficacy of the composition in treating the patient's alopecia.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 11-29 remain rejected under the judicially created doctrine of obviousness-type double patenting over patented claims 35-36 of U.S. Patent No. 6,187,817, already of record, for the reasons of record set forth at pages 16-19 of the previous Office Action dated March 8, 2006, of which said reasons are herein incorporated by reference.

Applicant traverses the rejection on the grounds that the patented claims are directed to methods of preventing or reducing alopecia that arises from treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound, and not as it results from radiation exposure.

Applicant's remarks have been fully considered, but are not persuasive.

It remains that the patented claims clearly provide for the administration of an anti-alopecia effective amount of D-methionine for the treatment of alopecia in a human, cat, or dog undergoing treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound. The major difference between the patented claims and the present claims lies in the fact that the patented claims are direction to the treatment of alopecia as it results from exposure to a chemotherapeutic effective amount of an anti-tumor platinum coordination compound, where the present claims are directed to the treatment of alopecia as it results from exposure to radiation for a time and at an intensity sufficient to result in alopecia.

While such a difference has been carefully considered, it fails to impart patentable distinction to the present claims over the patented claims because both the present claims and the patented claims are primarily directed to the treatment of alopecia. Regardless of how such a condition developed, both the present set of claims and the patented set of claims expressly teaches D-methionine for the treatment of the same condition (alopecia).

Furthermore, it is noted that the limitation directed to radiation exposure in the present claims does not directly impact the host at the time the compounds would have been administered to such a host. In other words, the host required for both the present claims and the patented claims is a subject that has alopecia. Whatever other circumstances that such a patient may have been exposed to prior to the treatment to induce such a condition does not impact the execution of the method as presently claimed because such circumstances occurred prior to the execution of the method and, therefore, do not limit the host. Additionally, the present claims do not preclude the treatment of patients receiving concomitant chemotherapeutic treatments. Thus, though the present claims and the patented claims may be different in this respect, it remains that such a difference does not patentably distinguish the present claims from those of the patent.

For these reasons, and those previously made of record at pages 16-19 of the previous Office Action dated March 8, 2006, rejection of claims 1-9 and 11-29 remains proper and is **maintained**.

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent No. 5,470,876 to Proctor ("Topical SOD for Treating Hair Loss").

Rejection of claims 1-9 and 11-29 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 8, 2006

Ardin H. Marschel 9/16/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER